

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Galdes, et al.

Serial No.: 09/325,602

Filed: June 3, 1999

Title: *Method and Compositions Treating Disorders Involving Excitotoxicity*



Atty. Docket:

BIV-069.02

Group Art Unit:

1653

Examiner:

F. Moezie

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**CERTIFICATE OF MAILING**

I hereby certify that the foregoing document is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, DC 20231 on this 14th day of August, 2000.

C. E. Coker  
Eugene Coker

**AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In response to the Restriction Requirement, which was mailed from the U.S. Patent and Trademark Office on July 31, 2000, in the above-identified patent application, Applicants elect with traverse Group I, drawn to methods of promoting the survival of cells. Applicants elect this invention with traverse, because the claims in Group I encompass subject matter of claims grouped by the Examiner in Groups II, III, IV, and V, and could thus be examined simultaneously without any additional burden.

In particular, Applicants respectfully point out that the claims of Group I are not limited to *in vitro* methods, contrary to the Examiner's assertion, but include within their scope contacting cells *in vivo* with a lipophilic modified hedgehog polypeptide. Thus, these claims include within their scope the subject matter of independent claims 5-8 and <sup>21</sup>20, which involve *in vivo* methods for treating or preventing a condition by administering a lipophilic modified

hedgehog polypeptide to a patient, as well as the subject matter of dependent claims 9-16. Applicants thus argue that all of the method claims should be examined together, and respectfully request that the Examiner combine these claims for examination, i.e., to examine claims 1-16 and 20 together. Examination of these claims simultaneously does not present an undue burden on the Examiner, because examination of Group I will necessarily entail searches relating to *in vivo* methods such as are claimed in claims 5-14, and 18, and thus will not increase the scope of the Examiner's searches.

The Examiner further requested that the Applicants elect a species and designate the claims readable thereon. Applicants provisionally elect, with traverse and for search purposes only, species A for Group I, a method for promoting the survival of neuronal cells. Applicants respectfully point out that the substantia nigra, dopaminergic cells, and GABAergic cells all comprise neuronal cells, and thus searches related to this group will necessarily entail searches related to species B, C, and D as well. Thus, an examination encompassing the four species identified by the Examiner presents no undue burden relative to the examination of species A alone, and thus Applicants traverse this requirement.

Finally, in response to the Examiner's request that an ultimate species be elected, Applicants elect octyl maleimide human Sonic hedgehog, e.g., as described in Example 7 of the Application. Applicants make this election for search purposes only.

Please enter the following amendments to the claims:

B1 1. (Amended) A method for promoting survival and/or functional performance of neuronal cells susceptible to excitotoxicity [exotoxicity], comprising contacting the cells with an amount of a lipophilic modified hedgehog polypeptide effective to reduce [exotoxin] the role of excitotoxin-mediated degradation of the cells.

B2 9. (Amended) The method of any of claims 1-8, wherein the hedgehog polypeptide is modified with one or more [serol] sterol moieties.